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FEB 23 2010

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Patent Department (150/05/43S)
150 East 42nd Street
New York, NY 10017-5755

In Re: Patent Term Extension
Application for
U.S. Patent No. 6,667,314

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 6,667,314, claims of which cover the human drug product SELZENTRY® (maraviroc), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 73 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of a request for reconsideration, the Director will issue a certificate of extension, under seal, for a period of 73 days.

The period of extension, if calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of February 10, 2009 (74 Fed. Reg. 6638), would be 776 days. Under 35 U.S.C. § 156(c):

Period of Extension	=	½ (Testing Phase) + Approval Phase
	=	½ (1,294 - 201) + 230
	=	776 days (2.1 years)

Since the regulatory review period began June 6, 2003, before the patent issued (December 23, 2003), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). (From June 6, 2003, to and including December 23, 2003, is 201 days; this period is subtracted from the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period.) No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

However, the 14 year exception of 35 U.S.C. § 156(c)(3) operates to limit the term of the extension in the present situation, because it provides that the period remaining in the term of the patent measured from the date of approval of the approved product plus any patent term extension cannot exceed fourteen years. The period of extension calculated above, 776 days, would extend the patent from May 25, 2021, to July 10, 2023, which is beyond the 14-year limit (the approval date is August 6, 2007, thus the 14 year limit is August 6, 2021). The period of

extension is thus limited to August 6, 2021, by operation of 35 U.S.C. § 156(c)(3). Accordingly, the period of extension is the number of days to extend the term of the patent from its original expiration date, May 25, 2021, to and including August 6, 2021, or 73 days.

The limitations of 35 U.S.C. 156(g)(6) do not operate to further reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.:	6,667,314
Granted:	December 23, 2003
Original Expiration Date[1]:	May 25, 2021
Applicant:	Manoussos Perros et al.
Owner of Record:	Pfizer Inc.
Title:	Tropan Derivatives Useful In Therapy
Product Trade Name:	SELZENTRY® (maraviroc)
Term Extended:	73 days
Expiration Date of Extension:	August 6, 2021

Any correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Hatch-Waxman PTE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450.

By FAX: (571) 273-7728

[1]Subject to the provisions of 35 U.S.C. § 41(b).

Telephone inquiries related to this determination should be directed to Raul Tamayo at (571) 272-7728.

Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Associate Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 51, Rm. 6222
Silver Spring, MD 20993-0002

Attention: Beverly Friedman

RE: SELZENTRY® (maraviroc)
Docket No.: FDA-2008-E-0194